K093650

Medtronic

FEB 17 2010

510(k) Summary

Date Prepared November 24, 2009

Submitter

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Establish Registration Number: 2184009

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Device Name and Classification

Trade Name:	BioTrend® Oxygen Saturation and Hematocrit System
Common Name:	Cardiopulmonary bypass in-line blood gas sensor.
Regulation Number:	21 CFR 870.4410
Product Code:	DTY
Classification:	Class II

Predicate Device

BioTrend® Oxygen Saturation and Hematocrit System (K954501)

Device Description

The modified BioTrend Oxygen Saturation and Hematocrit System is an on-line monitoring instrument that combines both venous (SvO2) and arterial (SaO2) oxygen saturation measurement with hematocrit (Hct) measurement. The BioTrend System consists of the BioTrend Instrument, two Sensor Cables, and a power cord. The BioTrend system is designed to be used with the Tri-optic Measurement Cells.

The Tri-optic Measurement Cell is a disposable device in the extracorporeal circuit that provides a sealed interface between the blood pathway and the BioTrend sensor cable. No change is being made to the Tri-optic Measurement Cell, which was previously cleared under K910421 and K012743.

Using fiber optic technology, the BioTrend System continuously measures the percentage of oxygen saturation and hematocrit and displays the results on large, easy-to-read, color-coded

Light Emitting Diodes (LEDs). The display panel indicates operating status and error messages, and provides a means for system calibration.

BioTrend Sensor Cables connect to the BioTrend instrument and the in-line Tri-optic Measurement Cells (TMC) to transmit optical measurement signals. The BioTrend sensor cables isolate the patient from the instrument electronics, providing patient protection. The BioTrend instrument contains a built-in, rechargeable battery pack to provide the battery power. Consequently, the BioTrend instrument can be operated on AC or battery power. A continuous, built-in self-check immediately alerts the operator of equipment failure and displays a corresponding error code.

Indications for Use

The BioTrend Oxygen Saturation and Hematocrit System measures percent oxygen saturation and hematocrit of the blood in the extracorporeal circuit. The extracorporeal circuit is used for, but is not limited to, cardiopulmonary bypass, closed-chest support, and limb perfusion.

Comparison to Predicate Device

A comparison of the modified product and the currently marketed oxygen saturation and hematocrit system has the following similarities to the system which received 510(k) clearance:

- Same intended use.
- Same operating principle.
- Same performance claims.
- Same Tri-Optic Measurement Cells (K910421 and K012743) for transmission of optical measurement signals.
- Same Algorithm used to calculate oxygen saturation and hematocrit.

Intended Use

The intended use is unchanged.

Labeling

A summary of the labeling changes is as follows:

- Update IFU and labeling to address hardware and software changes to the device.
- Add model number to device label.

Summary of Performance Data

Preclinical testing data were used to establish the performance characteristics of the modifications to this device. Clinical testing was not required to establish substantial equivalence. The following bench testing was conducted:

- Blood testing: to verify oxygen saturation and hemacrit measurement accuracy
- Environmental testing: to verify operational temperature, storage temperature, thermal shock, storage humidity, vibration, mechanical shock, cautery, defibrillation, spill resistance, and chemical resistance
- Packaging testing: to verify packaging requirements per ASTM D 4169 performance testing of shipping Containers and Systems, Distribution Cycle 13, Assurance Level 1.
- System testing: to verify the device meets the system level requirements called out in the system requirements document
- Software testing: to verify the device meets the software requirements called out in the software requirements document
- Hardware testing: to verify the PCB assemblies meet the performance requirements called out in the design specifications
- UL/TUV testing: to verify the device meets the emissions, immunity/susceptibility, and safety requirements

Conclusion

The modifications to the BioTrend® Oxygen Saturation and Hematocrit System described in this submission result in a substantially equivalent device because the fundamental scientific technology and the intended use are unchanged.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 17 2010

Medtronic Cardiovascular MVS83
c/o Mr. Jeffrey L. Koll
Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K093650
BioTrend® Oxygen Saturation and Hematocrit System
Regulation Number: 21 CFR 870.4410
Regulation Name: Sensor, Blood-Gas, In-Line, Cardiopulmonary Bypass
Regulatory Class: Class II
Product Code: DTY
Dated: January 13, 2010
Received: January 14, 2010

Dear Mr. Koll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093650

Device Name: BioTrend Oxygen Saturation and Hematocrit System

Indications for Use:

The BioTrend Oxygen Saturation and Hematocrit System measures percent oxygen saturation and hematocrit of the blood in the extracorporeal circuit.
The extracorporeal circuit is used for, but is not limited to,
cardiopulmonary bypass, closed-chest support, and limb perfusion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vichman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093650